

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | | |
|---|---|-------------------------------------|
| In re: PHARMACEUTICAL INDUSTRY |) | |
| AVERAGE WHOLESAL PRICE |) | |
| LITIGATION |) | MDL No. 1456 |
| |) | Civil Action No. 01-12257-PBS |
| |) | |
| THIS DOCUMENT RELATES TO: |) | Hon. Patti B. Saris |
| |) | |
| <i>United States of America, ex rel. Ven-a-Care</i> |) | Magistrate Judge Marianne B. Bowler |
| <i>of the Florida Keys, Inc., v. Abbott</i> |) | |
| <i>Laboratories, Inc.,</i> |) | |
| CIVIL ACTION NO. 06-CV-11337-PBS |) | |

EXHIBIT B

To the United States' Response to: (1) Third Party Hospira, Inc.'s Motion for a Protective Order and Motion to Quash Plaintiff's Third Party Subpoenas and (2) Defendant Abbott Laboratories, Inc.'s Motion for a Protective Order and Motion to Quash Plaintiff's Third Party Subpoenas

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001-2113
TELEPHONE: 202-879-3939 • FACSIMILE: 202-626-1700

Direct Number: (202) 879-5562
dstorborg@jonesday.com

JP259120
080024-024348

November 22, 2006

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Raedell Ashley
Utah Department of Health
Health Care Financing
P.O. Box 143102
Salt Lake City, UT 84114-3102

Re: *United States ex re. Ven-A-Care of the Florida Keys, Inc., et al., v. Abbott Laboratories, Inc. and Hospira, Inc., Civil Action No. 06-11337-PBS (D. Mass.)*

Dear Ms. Ashley:

Enclosed please find a subpoena served on behalf of Abbott Laboratories, Inc. that requests that you perform a search for and produce certain documents relevant to the above-referenced litigation. The litigation involves allegations by the United States government that, for the time period from 1991 through 2001, certain drug pricing information – such as Average Wholesale Price (“AWP”) – was inflated, that governmental payors were unaware of this inflation, and that this led the Medicare and state Medicaid programs to overpay for prescription drugs. The litigation involves 46 National Drug Codes (NDCs) and eleven HCPCS “J-Codes.” These drugs are defined in the subpoena as the “Subject Drugs” and “Subject J-Codes” and are listed on the attached Schedules A and B, respectively. The drugs involved include sterile water, sodium chloride solution, dextrose in water, and Vancomycin.

The enclosed subpoena requests that you search for and produce documents that are in your possession as well as documents that are within your control or are otherwise available to you, such as documents in the possession of Medicaid fiscal intermediaries and related Utah state agencies. See Exhibit B, Instruction No. 1. Generally speaking, the subpoena seeks documents relating to the amounts and methodologies at which the relevant drugs were reimbursed by the Utah Medicaid program (including claims data in electronic form), the Utah Medicaid program’s knowledge and understanding of drug pricing information such as AWP, the policies implemented by the Utah Medicaid program to control drug reimbursement costs, and the reasoning behind the state of Utah’s decisions concerning the reimbursement of drugs and related professional services. The specific documents requested are described in Exhibit A to the subpoena. Please see the Definitions and Instructions included as Exhibit B to the subpoena.

JONES DAY

Custodian of Records
November 22, 2006
Page 2

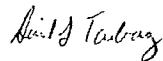
Recognizing your position as a third party to this litigation, we have attempted to tailor our requests for information narrowly. If you are uncertain whether the subpoena calls for particular categories of documents (particularly if those documents are voluminous), I encourage you to contact me directly for additional guidance. In addition, if the State of Utah has already produced some of the documents called for in the subpoena, please advise me of that production. The State does not need to re-produce documents it has already produced. Our goal is to limit our discovery to the relevant issues and, to the extent consistent with our obligation to defend the case vigorously, minimize the burden upon you.

The subpoena requests production of all responsive documents and data to my attention in Washington, D.C. by January 5, 2007. Consistent with our need to obtain discovery expeditiously, we are willing to discuss reasonable extensions that may be necessary to search for and produce certain categories of documents.

Finally, please notify me if the State of Utah has retained counsel that Abbott should work with to coordinate the State's response to Abbott's subpoena.

Thank you in advance for your cooperation, and please do not hesitate to contact me with any questions you may have regarding the subpoena.

Sincerely,



David S. Torborg

Enclosures

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---------------------------------|
| IN RE: PHARMACEUTICAL INDUSTRY |) | SUBPOENA IN A CIVIL CASE |
| AVERAGE WHOLESALE PRICE |) | |
| LITIGATION |) | MDL NO. 1456 |
| |) | |
| THIS DOCUMENT RELATES TO |) | Civil Action No. 06-CV-11337 |
| <i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i> |) | Lead Case No. 01-CV-12257 |
| <i>Inc., et al., v. Abbott Laboratories, Inc., et al.</i> |) | Judge Patti B. Saris |

Chief Magistrate Judge Marianne B. Bowler

TO: Utah Department of Health
Health Care Financing
P.O. Box 143102
Salt Lake City, UT 84114-3102

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY

COURTROOM

DATE AND TIME

☐ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION

DATE AND TIME

☒ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

Please see attached Exhibit A (Documents Requested) and Exhibit B (Definitions and Instructions).

PLACE

DATE AND TIME

January 5, 2007

JONES DAY
51 Louisiana Ave., N.W.
Washington, DC 20001
(202) 879-3939
dstorborg@jonesday.com

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

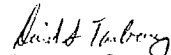
PREMISES

DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)

DATE


Attorney for Defendants Abbott Laboratories, Inc.

November 22, 2006

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER: David S. Torborg, Esq., Jones Day, 51 Louisiana Ave., N.W., Washington, DC 20001 (202) 879-3939

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO 88 (Rev. 1/94) Subpoena in a Civil Case

| PROOF OF SERVICE | | |
|------------------------|------|-------------------|
| SERVED | DATE | PLACE |
| SERVED ON (PRINT NAME) | | MANNER OF SERVICE |
| SERVED BY (PRINT NAME) | | TITLE |

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE_____
SIGNATURE OF SERVER_____
ADDRESS OF SERVER_____
Rule 45, Federal Rules of Civil Procedure, Parts C & D:

(C) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party service the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance;
- (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
- (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
- (iv) subjects a person to undue burden.

(B) If a subpoena

- (i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
- (ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
- (iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

EXHIBIT A

DOCUMENTS REQUESTED

1. For the time period January 1, 1985 to December 31, 2001, Documents (such as current or historical organizational charts) sufficient to identify those individuals within the Utah DH involved in (a) establishing the methodologies or formulas used to determine reimbursement for drugs and the administration or dispensing of drugs by the Utah Medicaid program or (b) the price at which any agency or department of the State of Utah purchased drugs directly or indirectly from Manufacturers, wholesalers, or distributors.

2. From January 1, 1991 to the present, all state Medicaid plans filed by Utah under 42 U.S.C. § 1396(a) and, to the extent they relate to the reimbursement of drugs or the administration or dispensing of drugs, all proposed or actual amendments to those plans, all materials created or maintained pursuant to 42 C.F.R. § 447.333 (including supporting materials or data), and all Communications with, or administrative or judicial proceedings by, the U.S. Government concerning those state plans or amendments.

3. From January 1, 1991 to the present, Documents sufficient to identify the methodologies or formulas used to determine the Utah Medicaid program's reimbursement for the Subject Drugs and the Subject J-Codes, including but not limited to all fee schedules, reimbursement tables, and reimbursement manuals. If different methodologies or formulas were used depending on the drug, time period, fiscal intermediary, and whether the drug was reimbursed based upon an NDC reimbursement basis or J-Code reimbursement basis, You are requested to provide Documents sufficient to identify those differences.

4. For the time period from January 1, 1991 to December 31, 2001, for each instance that the Utah Medicaid program provided reimbursement of a claim relating to the dispensing of the Subject Drugs, complete claims data with related file layouts, field definitions, data dictionaries, source tables, relationship tables, and business rules. These data are requested in electronic form used by SQL Server, Microsoft Access, Microsoft Excel, or a delimited file that can be readily uploaded into one of those programs. The complete claims data requested include all fields, other than individual patient identifiers, contained on the Provider's claim submission and all additional fields added to process the claim, including:

- (a) *Identifier*: claim number, sequence number representing each line item of the claim, and other identifying information;
- (b) *Provider type*: pharmacy, physician, physician supplier, outpatient care provider, home health provider, institutional pharmacy, physician crossover, etc.;
- (c) *Claim Type*: any available claim type information, including but not limited to any information that indicates whether Utah Medicaid is the secondary payor including Medicare Crossover Claims;

- (d) *Transaction Type*: all available transaction type information, such as correction, cancellation, etc., identifiers, and source transaction information (*e.g.*, if one claim corrects another claim, information about which claim is being corrected);
- (e) *Status*: all status information, including the payment code indicating whether the claim has been accepted, processed, and/or paid and the type of program the claim will be processed under (*e.g.*, Medicaid, Managed Care, etc.);
- (f) *Dates*: all available dates, including the date service was provided, the date the claim was received, and the date the claim was paid;
- (g) *Basis of payment*: coding within the claim payment transaction which identifies the reference point from which the claim payment amount is determined (*e.g.*, AWP, usual & customary, EAC, FUL, MAC, Billed Amount, Charges, etc.);
- (h) *Product*: all product information, including:
 - (i) NDC. Please provide all 11 digits (do not drop leading or trailing 0's) and ideally in three separate fields – labeler (first five digits), product (next four digits) and package size (final two digits);
 - (ii) Name;
 - (iii) Type (*e.g.*, single source, multi-source);
 - (iv) Therapeutic class; and
 - (v) Related items like diagnosis codes, place of service, and type of service (where relevant).
- (i) *Units*: all units information with decimals in the correct position, including submitted units, allowed units, and unit of measure (*e.g.*, capsule vs. bottle, milliliter, etc.);
- (j) *Other Data for Payment*: any other data used to determine the amount of the payment not listed above (*e.g.*, channel of procurement, etc.);
- (k) *Payments*: all fields related to billed amounts, payment limit amounts, allowed amount, and actual amounts paid along with the bases for the payment, all with decimals in the correct position, including:
 - (i) Billed charges;
 - (ii) Basis of payment (*e.g.*, billed charges, ingredient cost, EAC, FUL, MAC, Billed Amount, acquisition cost, AWP, WAC, etc.);

- (iii) Dispensing fee;
 - (iv) Service administration fee (*e.g.*, provider service fees);
 - (v) Allowed amount or contracted amount;
 - (vi) Any other payment amount (*e.g.*, inventory management fee/profit factor, delivery fee, generic incentive fee, etc.);
 - (vii) Any amounts used to reduce amount paid (*e.g.*, payments received from other payors and the number, name, and other information associated with such payors, co-insurance, co-payment, deductible); and
 - (viii) Amount paid.
- (l) *Comments:* all other memo or free-form fields.

5. Documents concerning your relationship with any third parties performing claims processing or payment of Medicaid claims services for You, including but not limited to contracts, fee schedules, and processing manuals.

6. For the time period from January 1, 1991 to December 31, 2001, examples of each type of claim form used by Providers to seek reimbursement from the Utah Medicaid program for the Subject Drugs or Subject J-Codes, whether reimbursed on an NDC reimbursement basis or a J-Code reimbursement basis, including but not limited to screen shots from any Point of Sale System.

7. For the time period from January 1, 1991 to December 31, 2001, Documents sufficient to show if and how the Utah Medicaid program applied any MAC, state MAC, FUL, or other maximum payment amount when reimbursing any of the Subject Drugs or Subject J-Codes.

8. From January 1, 1985 to the present, any data, report, testimony, audit, study, analysis, or survey (whether completed or not) relating to (a) the methodologies or formulas used to determine reimbursement for drugs or the administration or dispensing of drugs, (b) the acquisition costs of Providers for drugs, (c) the difference between AWP and acquisition cost for any drug, or (d) the cost of Providers to dispense or administer drugs.

9. From January 1, 1985 to the present, all Communications between You and the U.S. Government, any other state Medicaid program, any Medicaid fiscal intermediary, any Medicare contractor, NAMFCU, any MFCU, any Publisher, any Provider, the National Association of State Medicaid Directors, the National Governors' Association, or Ven-A-Care concerning (a) the methodologies or formulas to be used in determining reimbursement for drugs or the administration or dispensing of drugs (such as Program Memoranda, National Coverage

Decisions, Local Medical Review Policies, Bulletins, newsletters meetings, seminars, circulars, governmental reports, or any transmission of data), (b) the acquisition costs of Providers for drugs, (c) the difference between AWP and acquisition cost for any drug, or (d) the cost of Providers to dispense or administer drugs. This request includes but is not limited to all memoranda, reports or data provided by the CMS/HCFA, United States Department of Health and Human Services – Office of Inspector General, and the General Accounting Office.

10. For the time period from January 1, 1985 to December 31, 2001, Documents sufficient to identify those individuals within the Utah DH with responsibility for reviewing all memoranda, reports, or data provided by the CMS/HCFA, United States Department of Health and Human Services – Office of Inspector General, and the General Accounting Office relating to Medicare or Medicaid reimbursement of prescription drugs.

11. For the time period from January 1, 1991 to December 31, 2001, all data or other information provided to the United States Department of Health and Human Services – Office of Inspector General or the General Accounting Office relating to reports or studies concerning Medicare or Medicaid reimbursement of prescription drugs or the dispensing or administration drugs.

12. For the time period from January 1, 1991 to December 31, 2001, all Documents concerning any attempt to determine or calculate EAC for any of the Subject Drugs or Subject J-Codes.

13. For the time period from January 1, 1991 to December 31, 2001, Documents sufficient to identify the amounts at which the Utah Medicaid program reimbursed 340B Providers for the ingredient cost of the Subject Drugs.

14. For the time period from January 1, 1985 to December 31, 2001, all Documents concerning the meaning and calculation of AWP, WAC, EAC, List Price, Direct Price or actual acquisition cost, including all Documents related to Your understanding of these figures and Your consideration of whether to use any of these figures in determining reimbursement of drugs.

15. From January 1, 1985 to the present, all Communications between You and any Manufacturer, Provider, lobbying firm, professional or trade group, patients' rights group, law firm, or any other non-government organization relating to the methodologies or formulas used to determine reimbursement of drugs or professional services associated with the dispensing or administration of drugs.

16. From January 1, 1991 to the present, all Documents relating to any proposal to change the Utah Medicaid program's reimbursement for professional services associated with the dispensing or administration of drugs.

17. From January 1, 1985 to the present, all Documents concerning whether the payment formula for the drug ingredient cost could serve as a means of subsidizing or offsetting perceived or asserted under-reimbursement for professional services associated with the dispensing or administration of drugs under Medicaid, or as a mechanism to encourage treatment outside of the hospital setting.

18. All Documents relating to revised drug pricing information provided by NAMFCU and the United States Department of Justice to First DataBank on or around February 2000, including but not limited to all Documents concerning whether and how the Utah Medicaid program utilized the revised pricing information.

19. From January 1, 1991 to the present, all Communications relating to AMP information, as well as Documents sufficient to identify those individuals within the Utah DH who had access to or actual knowledge of the AMPs for the Subject Drugs.

20. From January 1, 1991 to the present, all Documents concerning whether and how the Utah Medicaid program has utilized AMP information in the reimbursement of drugs.

21. From January 1, 1991 to the present, all Documents concerning any comparison of AMP information and AWP, WAC, List Price, Direct Price, or the amount at which the Utah Medicaid program reimbursed for drugs.

22. All Documents that reflect any supplemental or additional rebates (*i.e.*, a rebate other than provided for under the Medicaid Drug Rebate Program) requested or received from any Manufacturer, including any legislative or regulatory proposal regarding supplemental or additional rebates from any Manufacturer.

23. From January 1, 1991 to the present, all Documents produced by any Medicaid fiscal intermediary, Publisher, Provider, or other Person to You in connection with any investigation of drug pricing. This includes any documents provided by Ven-A-Care.

24. From January 1, 1991 to the present, all Documents concerning any lawsuit, proceeding, or investigation concerning the pricing or reimbursement of drugs at which Your employees or agents have testified, provided statements, or been interviewed.

25. From January 1, 1995 to the present, all Communications between You and the United States Department of Justice, the United States Department of Health and Human Services – Office of Inspector General, or NAMFCU relating to any lawsuit, proceeding, or investigation concerning the pricing or reimbursement of drugs.

26. Any representation that Abbott made directly to You regarding pricing or reimbursement for drugs.

27. Documents sufficient to describe Your Document retention or destruction policies, including any changes to, or departures from, such policies, and Documents demonstrating that You have complied with such policies, including but not limited to document preservation notices and litigation hold orders circulated by You.

EXHIBIT B

DEFINITIONS AND INSTRUCTIONS

Definitions

1. "Abbott" means Abbott Laboratories, Inc. and Abbott Laboratories and any of their past or present officials, officers, representatives, agents, assigns, attorneys, employees, divisions, departments, agencies, affiliates, subsidiaries, and all other persons or entities acting or purporting to act on their behalf or under their control.
2. "AMP" or "Average Manufacturer Price" shall have the meaning set forth in 42 U.S.C. § 1396r-8(k)(1).
3. "AWP" or "Average Wholesale Price" means any figures so categorized and periodically published by any Publisher.
4. "CMS/HCFA" means "Centers for Medicare and Medicaid Services," its predecessor agencies, including the Health Care Financing Administration ("HCFA"), and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.
5. "Communication" means any oral or written exchange of words, thoughts or ideas to another person or entity, whether in person, in a group, by telephone, by letter, by telex or by any other process, electric, electronic or otherwise. All such communications in writing shall include, without limitation, printed, typed, handwritten, or other readable documents, whether in hardcopy, electronic mail or stored electronically on a computer disk or otherwise, contracts, correspondence, diaries, drafts (initial and all subsequent), forecasts, invoices, logbooks, memoranda, minutes, notes, reports, statements, studies, surveys and any and all non-identical copies thereof.
6. "Concern," "concerning," "relating to," or "relate to" means refer to, regard, concern, describe, explain, state, evidence, record, constitute, pertain to, reflect, comprise, contain, embody, mention, show, support, contradict, and discuss, whether directly or indirectly, as required by the context to bring within the scope of the requests in this request for production of documents any documents that might be deemed outside their scope by another construction.
7. "Documents" means all original written, recorded, or graphic matters whatsoever, and any and all non-identical copies thereof, including but not limited to advertisements, affidavits, agreements, analyses, applications, appointment books, bills, binders, books, books of account, brochures, calendars, charts, checks or other records of payment, communications, computer printouts, computer stores data, conferences, or other meetings, contracts, correspondence, diaries, electronic mail, evaluations, facsimiles, files, filings, folders, forms,

interviews, invoices, jottings, letters, lists, manuals, memoranda, microfilm or other data compilations from which information can be derived, minutes, notations, notebooks, notes, opinions, pamphlets, papers, photocopies, photographs or other visual images, policies, recordings of telephone or other conversations, records, reports, resumes, schedules, scraps of paper, statements, studies, summaries, tangible things, tapes, telegraphs, telephone logs, telex messages, transcripts, website postings, and work papers, which are in the possession of the Carrier as defined above. A draft or non-identical copy is a separate document within the meaning of this term.

8. "EAC" or "Estimated Acquisition Cost" shall have the meaning set forth in 42 C.F.R. § 447.301

9. "FUL" means "Federal Upper Limit" and shall have the meaning ascribed to that term pursuant to 42 C.F.R. § 447.332.

10. "J-Code reimbursement basis" refers to the reimbursement of drugs through use of a subset of the HCPCS code set with a high-order value of "J" (compare to "NDC reimbursement basis").

11. "MAC" or "Maximum Allowable Cost" shall have the meaning set forth in 42 C.F.R. § 447.332.

12. "Manufacturer" means a company that manufactures pharmaceutical products.

13. "Medicaid" means and refers to the jointly-funded Federal-State health insurance program enacted in 1965 as an amendment to the Social Security Act to pay for the costs of certain medical services and care.

14. "Medicaid Crossover Claim" means claims for which Medicare is the primary payor and Utah Medicaid is the secondary payor.

15. "Medicaid Drug Rebate Program" means and refers to the program established by the Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8, as amended by the Veterans Health Act of 1992, whereby drug manufacturers have national drug rebate agreements with HHS and a pricing agreement with HHS for the Public Health Service Section 340B Drug Pricing Program.

16. "MFCU" means individual state Medicaid Fraud Control Units, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

17. "NAMFCU" means National Association of Medicaid Fraud Control Units and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

18. "NDC reimbursement basis" refers to the reimbursement of drugs based on a Provider's submission of a National Drug Code ("NDC") (compare to "J-code reimbursement basis").

19. "Utah DH" means the Utah Department of Health.

20. "Person" means any natural person or any business, legal, or governmental agency or association.

21. "Point of Sale System" means a computer-transmitted claims processing system used by Providers to submit claims to Utah Medicaid.

22. "Provider" or "Providers" means and refers to any and all persons or entities that render health care services, including but not limited to pharmacists, institutional pharmacies, home health agencies, physicians, nurses, nurse practitioners, physicians' assistants, specialty pharmacy, nursing home personnel, laboratory technicians, x-ray and other medical equipment technicians, and other hospital or physician-office personnel.

23. "Publisher" or "Publishers" refers to Red Book, First DataBank, Blue Book, and Medi-Span, their predecessors and successors, and all employees, agents, consultants, accountants, or attorneys of any of the foregoing.

24. "You" or "Your" refers to the Utah DH and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

25. "Subject Drugs" means and refers to those drugs listed on attached Schedule A.

26. "Subject J-Codes" means those J-Codes identified in attached Schedule B.

27. "U.S. Government" means and refers to all legislative and executive branches, agencies, departments, or committees of the United States Government, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing. U.S. Government includes but is not limited to CMS/HCFA, Congress, Department of Commerce, Department of Defense, Department of Justice, Department of Health and Human Services, Department of Health and Human Services-Office of Inspector General, Department of Veterans Affairs General Accounting Office, Medicare Payment Advisory Commission (MedPac), Office of Management and Budget, Office of Pharmacy Affairs/Pharmacy Affairs Branch, and Pharmacy Support Services Center.

28. "Ven-A-Care" means Ven-A-Care of the Florida Keys, Inc., a corporation organized under the laws of Florida, and all predecessor or successor corporations, and any of its past or present officials, officers, representatives, agents, assigns, attorneys, employees,

divisions, departments, agencies, affiliates, subsidiaries, and all other persons or entities acting or purporting to act on its behalf or under its control.

29. "WAC" means "Wholesale Acquisition Cost."

30. "340B Provider" means and refers to any provider described in Section 340B of the Public Health Act, 42 U.S.C. § 256(b).

31. The terms "and" and "or" shall mean "and/or."

32. Any word written in the singular shall include the plural and vice versa.

33. In case of doubt as to the scope of a clause including "and," "or," "any," "all," "each," and "every," the intended meaning is inclusive rather than exclusive.

Instructions

1. These requests seek responsive documents in the possession of the Utah DH as well as any responsive documents that are within Your control or are otherwise available to You, such as documents in the possession of Medicaid fiscal intermediaries and related Utah state agencies.

2. If any document was but is no longer in Your possession, custody, or control, or was known to You, but is no longer in existence, please state, as to each document, its date, author(s), recipient(s) and what disposition was made of it or what became of it.

3. When an objection is made to any request or any subpart thereof, please state with specificity the part or subpart of the document request considered to be objectionable and all grounds for the objection.

4. If You find the meaning of any term in these document requests to be unclear, please assume a reasonable meaning, state what that assumed meaning is, and answer the request on the basis of that assumed meaning.

5. Each request for documents seeks production of the document in its entirety, without abbreviation or redaction, including all attachments or other matters affixed thereto.

6. With respect to each document that is withheld from production for any reason, or any portion of any document that has been redacted for any reason in connection with the production of a document, please provide a statement setting forth:

- (a) its date;
- (b) its title;

- (c) its author;
- (d) its addressee;
- (e) the identify of each person who received and/or saw the original or any copy of such document
- (f) the specific privilege under which it is withheld;
- (g) its general subject matter;
- (h) its present custodian; and
- (i) description of it that You contend is adequate to support that contention that it is privileged.

7. With respect to any conversation for which a privilege is being asserted, please identify by stating the following:

- (a) when and where the conversation occurred;
- (b) the name, title and job or position of each person who present at or during the conversation whether or not such conversation was in person or by telephone;
- (c) a brief description of the conversation's subject matter;
- (d) the statute, rule or decision that is claimed to give rise to the privilege; and
- (e) the name, title and job or position of all persons on whose behalf the privilege is asserted.

8. All documents are to be produced as they are kept in the usual course of business, their relative order in such files, and how such files were maintained. All electronic files should be produced where possible in electronic form, along with any software needed to access the information contained in the file and appropriate legends, keys, or other information needed to access and understand the data.

SCHEDULE 1: SUBJECT DRUGS

| <u>National Drug Code</u> | <u>Drug Description</u> |
|----------------------------------|---|
| 00074-1966-07 | BACTERIOSTATIC NACL INJECTION |
| 00074-3977-03 | BACTERIOSTATIC WATER FOR INJ. |
| 00074-4332-01 | STERILE VANCOMYCIN HYDROCHLORIDE INJECTION |
| 00074-4887-10 | STERILE WATER FOR INJECTION |
| 00074-4887-20 | STERILE WATER FOR INJECTION |
| 00074-4887-50 | STERILE WATER FOR INJECTION |
| 00074-4888-10 | SODIUM CHLORIDE INJECTION |
| 00074-4888-20 | SODIUM CHLORIDE INJECTION |
| 00074-6138-02 | SODIUM CHLORIDE IRRIGATION |
| 00074-6138-03 | SODIUM CHLORIDE IRRIGATION |
| 00074-6138-22 | SODIUM CHLORIDE IRRIGATION |
| 00074-6139-02 | STERILE WATER FOR IRRIGATION |
| 00074-6139-03 | STERILE WATER FOR IRRIGATION |
| 00074-6139-22 | STERILE WATER FOR IRRIGATION |
| 00074-6509-01 | STERILE VANCOMYCIN HYDROCHLORIDE |
| 00074-6533-01 | STERILE VANCOMYCIN HYDROCHLORIDE |
| 00074-6534-01 | STERILE VANCOMYCIN HYDROCHLORIDE ADD-VANTAGE VIALS |
| 00074-6535-01 | STERILE VANCOMYCIN HYDROCHLORIDE ADD-VANTAGE VIALS |
| 00074-7100-13 | DEXTROSE INJECTION |
| 00074-7100-23 | DEXTROSE INJECTION |
| 00074-7101-02 | SODIUM CHLORIDE INJECTION |
| 00074-7101-13 | SODIUM CHLORIDE INJECTION |
| 00074-7101-23 | SODIUM CHLORIDE INJECTION |
| 00074-7120-07 | DEXTROSE INJECTION |
| 00074-7138-09 | SODIUM CHLORIDE IRRIGATION |
| 00074-7139-09 | STERILE WATER FOR IRRIGATION |
| 00074-7902-09 | 5% DEXTROSE AND 0.45% NACL WITH 0.15% KCL INJECTION |
| 00074-7922-02 | DEXTROSE INJECTION |
| 00074-7922-03 | DEXTROSE INJECTION |
| 00074-7922-09 | DEXTROSE INJECTION |
| 00074-7923-23 | DEXTROSE INJECTION |
| 00074-7923-36 | DEXTROSE INJECTION |
| 00074-7923-37 | DEXTROSE INJECTION |
| 00074-7924-09 | 5% DEXTROSE AND 0.225% NACL INJECTION |
| 00074-7926-09 | 5% DEXTROSE AND 0.45% NACL INJECTION |
| 00074-7941-09 | 5% DEXTROSE AND 0.9% NACL INJECTION |
| 00074-7972-05 | SODIUM CHLORIDE IRRIGATION |
| 00074-7973-05 | STERILE WATER FOR IRRIGATION |
| 00074-7983-02 | SODIUM CHLORIDE INJECTION |
| 00074-7983-03 | SODIUM CHLORIDE INJECTION |
| 00074-7983-09 | SODIUM CHLORIDE INJECTION |
| 00074-7984-23 | SODIUM CHLORIDE INJECTION |
| 00074-7984-36 | SODIUM CHLORIDE INJECTION |
| 00074-7984-37 | SODIUM CHLORIDE INJECTION |
| 00074-7985-09 | SODIUM CHLORIDE INJECTION |
| 00074-7990-09 | STERILE WATER FOR INJECTION |

SCHEDULE 2: SUBJECT J-CODES**HCPCS (J-Code)****Drug Description**

| | |
|-------|---|
| J2912 | SODIUM CHLORIDE, .9 PERCENT, PER 2 ML |
| J3370 | VANCOMYCIN HCL, 500 MG |
| J7030 | NORMAL SALINE SOLUTION, 1000 CC |
| J7040 | NORMAL SALINE SOLUTION, 500 ML |
| J7042 | 5 PERCENT DEXTROSE/NORMAL SALINE SOLUTION, 500 ML |
| J7050 | NORMAL SALINE SOLUTION, 250 CC |
| J7051 | STERILE SALINE OR WATER, UP TO 250 CC |
| J7060 | 5 PERCENT DEXTROSE/WATER, 500 ML |
| J7070 | D-5-W, 1000 CC |
| J7110 | DEXTRAN 75, 1000 ML |
| J7130 | HYPERTONIC SALINE SOLUTION, 50 OR 100 MEQ, 20 CC VIAL |